



VALIDATION OF MOLECULAR DIAGNOSTICS FOR THE MEASLES AND MUMPS VIRUSES

LPAC Meeting
May 23rd, 2013
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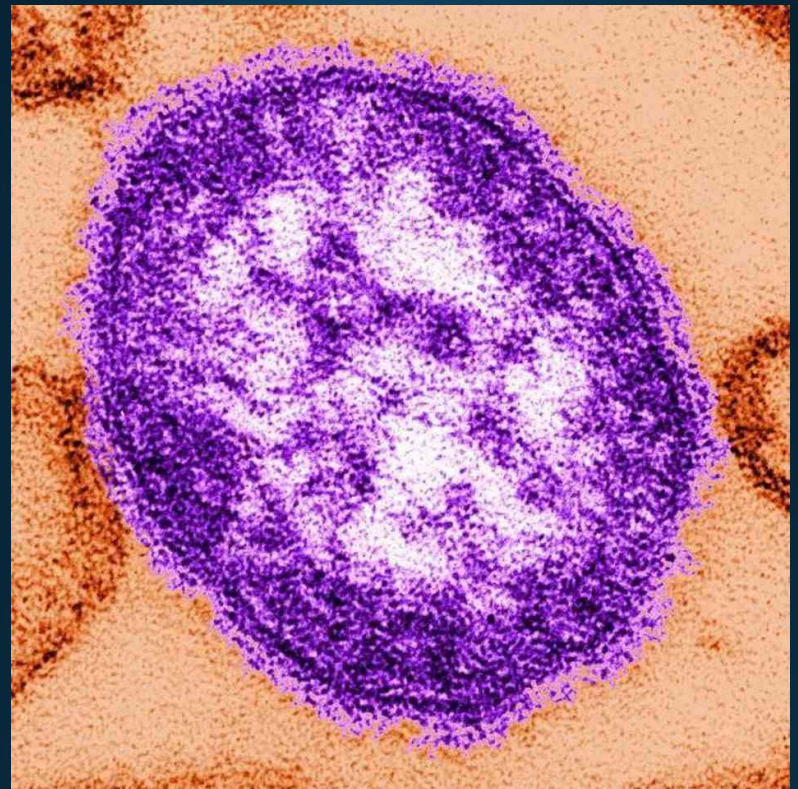


Introduction

- Measles
 - Vaccine preventable disease
 - Incubation 7-14 days
 - Clinical signs/symptoms: Blotchy rash, fever, cough, runny nose, conjunctivitis, malaise, Koplik's spots
- Mumps
 - Vaccine preventable disease
 - Incubation 16-18 days
 - Clinical signs/symptoms: fever, headache, muscle aches, fatigue, anorexia, swollen and tender salivary glands under the ears on one or both sides

Validation of Molecular Method- Measles

- All validation specimens were prepared from vaccine strains grown in cell culture
- Extracted using automated extraction instrument
- Tested for measles virus N-gene
- Human RNase P cellular reference gene



Validation of Molecular Method- Mumps

- All validation specimens were prepared from vaccine strains grown in cell culture
- Extracted using automated extraction instrument
- Tested for mumps virus N-gene
- Human RNase P cellular reference gene





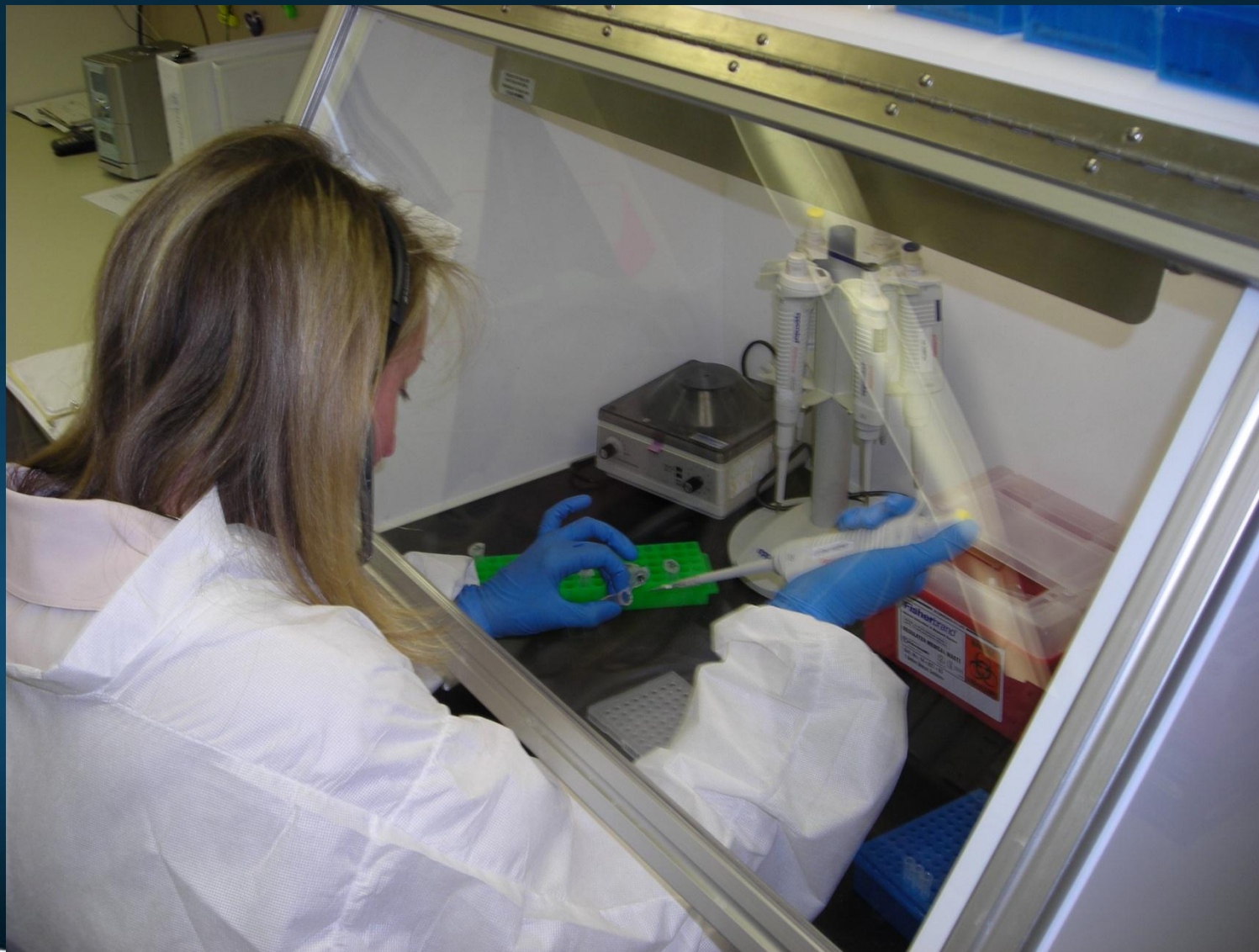
Validation Methods:

- **Accuracy:** Achieve the expected result for all spiked samples
- **Precision:** Compare CT values of 10 different specimens run by 3 different technicians on rRT-PCR in the same day
- **Analytical sensitivity:** Run a series of dilutions of both sample matrices (urine and nasopharyngeal swabs) spiked with synthetic virus control.
- **Reportable Range:** positive, negative, inconclusive, or invalid

Sample Extraction



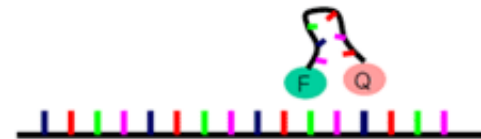
Plate Preparation



Nucleic acid amplification



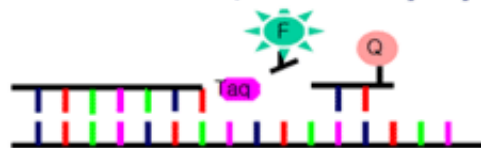
1. Denaturation Step



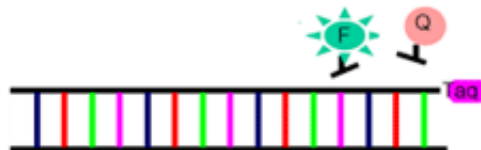
2. Probe Hybridization



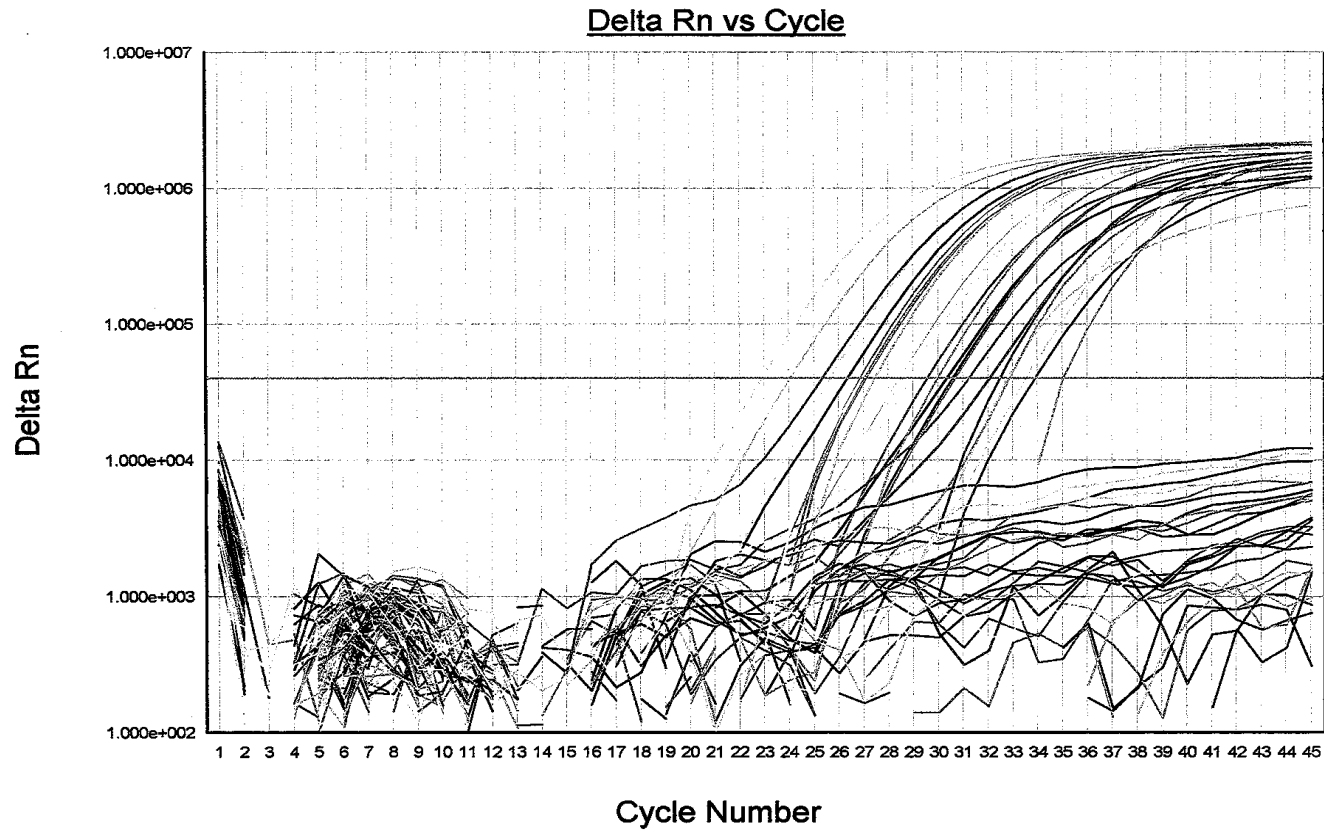
3. Extension / Probe Hybridization



4. Fluorescence emission



Result analysis



Selected Detector: All
Well(s): A1-H12

Impact

- Faster and more accurate than traditional diagnostics
- Core function and responsibility of DPHL, as a public health lab, to maintain testing capability for rare and vaccine preventable diseases.



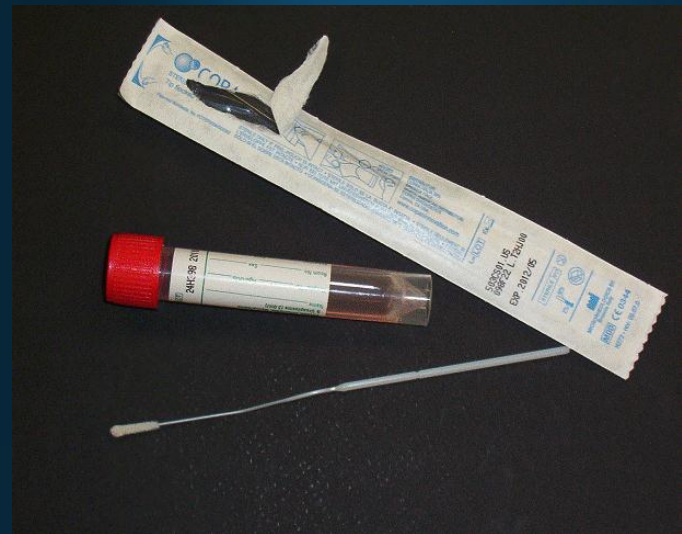
DELAWARE HEALTH AND SOCIAL SERVICES

Division of Public Health

Laboratory

Submitting Specimens to DPHL

- Contact Division of Epidemiology
- Acceptable specimen types:
 - Nasopharyngeal swabs
 - Urine



Questions?

